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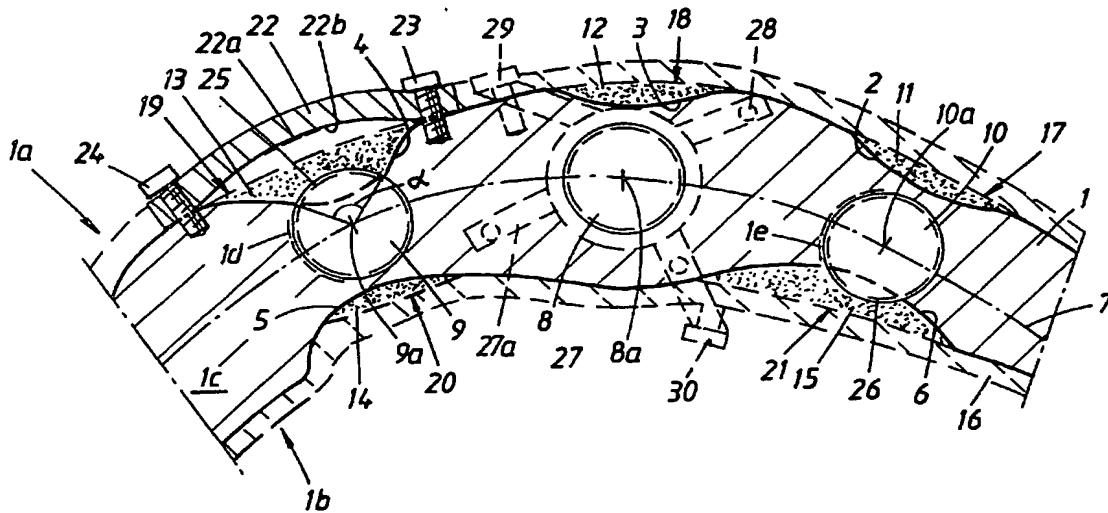
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ARRANGEMENT OF TWO OR MORE IMPLANTS PROVIDED WITH GROWTH-STIMULATING SUBSTANCE(S)



(57) Abstract: Two or more implants (8, 9, 10) are arranged in succession in the jaw bone (1) and bear or comprise growth-stimulating substances (25), here called GSS, which, as a function of secretion of body fluid at the implants, are intended to be released and form new bone (11-15) around the implants. The implants are designed to work with a release process for GSS, creating a leveling-out effect along the extent of the jaw bone in the horizontal and/or vertical direction and/or a leveling-out effect in the vertical direction. In this way it is possible to achieve optimum positions for the implants without the risk of compromised esthetics.

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Arrangement of two or more implants provided with growth-stimulating substance(s).

The present invention relates to an arrangement of two or more implants arranged in succession in the jaw bone and bearing or comprising growth-stimulating substance(s), here called GSS, which, as a function of secretion of body fluid at the implants, is/are intended to be released and form new bone around the implants.

It has been proposed that GSS be applied to implants so that, when the implants are in their positions fitted in the jaw bone holes, the GSS is released and builds up a new bone structure which is intended to increase the stability of the implant and/or optimize the appearance around the implant.

Reference may be made in this connection to patent applications SE 9901972-1 and WO 00/72778 filed by the same Applicant and inventor. Reference may also be made to the article published by, inter alia, the inventor of the present patent application and entitled "Properties of a New Porous Oxide Surface on Titanium Implants, Volume 1: The Oxidized Titanium Surface, Applied Osseointegration Research".

Examples of GSS which may be mentioned are matrix molecules, growth factors and differentiation factors and/or peptides with growth-stimulating properties.

In practical work on fitting implants in jaw bone, it has been proposed that the implants should be placed in the jaw bone at sites where the condition of the jaw bone in the initial stage is best or acceptable. In the case of completely or partially defective or irregular jaw bones, this has meant that the implant has been given a location which is not advantageous for the dental construction to be applied to the implant and

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which has a negative impact on the construction in question. In the worst cases, this can mean that the patient has to do without the desired dental construction. There is also a requirement that a  
5 degenerated jaw bone can be provided with implants used for supporting the dental construction. The present invention aims to solve these problems among others.

In connection with the function for forming new bone,  
10 problems may arise in obtaining the correct spatial distribution of newly formed bone in the jaw bone. According to the present invention, it is proposed that the jaw bone's soft tissue, with or without periosteum and/or a possible strengthening element, for example a  
15 polymer membrane, will protect the implant or implants during the formation of new bone. In this connection, problems may arise in correctly using the soft tissue and possible periosteum and/or strengthening element. The invention aims to solve these problems too.  
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There is therefore a need to be able to extend the choices available to the surgeon, dentist or other user with respect to the locations of the implants and of the jaw bone holes for these, despite the requirement  
25 that the stability of the implants must be maintained and that this stability must be comparable to that obtained in cases where the implant and associated hole are arranged in more solid jaw bone. In dental fixtures of the type in question, there is also a requirement to  
30 obtain a fixture which is of high quality from the point of view of appearance. The invention solves these problems too.

The feature which can principally be regarded as  
35 characterizing the invention is that the implants are designed to work with a release process for the growth-stimulating substance or substances GSS, permitting a leveling-out effect along the extent of the jaw bone in

the horizontal and/or vertical direction and/or a level-raising effect in the vertical direction.

In further developments of the invention, the latter is intended to be able to function for jaw bones which have one or more recesses in the horizontal plane. One or more first implants can in this case be arranged at one or more recesses. The release function can preferably be arranged so that it is greater on or at the implant or implants fitted at the recess or recesses compared to the implant or implants arranged at a higher portion or higher portions of the jaw bone. In one embodiment, the release function is to be arranged to cause or bring about a level increase along the whole jaw bone. In an initial stage, the implant is covered with the jaw bone's soft tissue so that inner spaces are formed at each implant and at parts of the jaw bone and its soft tissue. A strengthening element can in this case be used in conjunction with the jaw bone and soft tissue, possibly with periosteum, so that no collapse takes place in the initial stage and the stage of incorporation. The strengthening elements (for example polymer membranes or membranes made of metal (titanium)) can be of a temporary or permanent nature and can in some cases be secured to the jaw bone by means of securing members, for example screws, etc. The strengthening element or strengthening elements can be provided with projecting parts via which each strengthening element can be anchored in the jaw bone, by means of screws for example.

Further embodiments are set out in the attached dependent claims.

By means of the invention, it is possible, in connection with the fitting of implants, to obtain high-quality new bone formations so that they permit a compensating effect, for example both in the horizontal

plane of the jaw bone and in the vertical plane/vertical planes (on the outsides and/or insides of the jaw bone). The work can be carried out with essentially known means and techniques. GSS can be applied to implants with threads and/or outsides which have been provided with porous oxide layers with pores for storing GSS. The GSS forming the new bone structure can, if so desired, be combined with autologous bone, allogenic bone, xenografts and/or synthetic substances or materials available on the general market.

A presently proposed embodiment of an arrangement having the features characteristic of the invention will be described below with reference to the attached drawings, where

Figure 1 shows, in horizontal section, a lower jaw bone in which implants have been fitted and new bone formations have been initiated so that compensating effects in the horizontal plane of the jaw bone, i.e. the plane coinciding with the plane of the figure in Figure 1, have been created, and where a strengthening element has been shown in connection with the implants and the jaw bone,

Figure 2 shows, in vertical section, implants arranged in or at irregularities in the jaw bone, one of the implants having been provided with a strengthening element, and the newly formed bone portions have created a level-compensating effect in the vertical direction or horizontal direction of the jaw bone, and

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Figure 3 shows, in a diagrammatic side view, the new bone formation function having the effect of raising the level of the lower jaw.

In Figure 1, a lower jaw bone is shown diagrammatically by 1. The lower jaw bone has defects or irregularities 2, 3, 4, 5, 6 along its side surfaces 1a, 1b extending substantially at right angles to the plane of the figure in Figure 1 or inclined slightly from the bottom upward where they merge into the top surface 1c of the jaw bone 1. The main center line of the jaw bone is shown by 7. There is a need for implants to be able to be arranged substantially centrally around this center line, viewed in the horizontal plane according to Figure 1. A first implant 8 has a vertical axis 8a which coincides with the arc-shaped line 7. A second implant 9 is arranged in the jaw bone such that its longitudinal axis extends substantially vertically through the center line 7. The implant 10 also has its vertical axis 10a arranged in said arc-shaped line 7. The implants can be arranged substantially vertically in the jaw bone or can slope slightly in the latter.

The implants are arranged in formed/drilled jaw bone holes, the jaw bone holes for implants 9 and 10 being shown diagrammatically with reference numbers 1d and 1e. The optimum implant positioning in the jaw bone shown in Figure 1 means that the implant 8a lies near the defect or irregularity 3. The implant 9 is arranged at the defects or irregularities 4 and 5. Similarly, the implant is arranged at the defects or irregularities 2 and 6. There is therefore a need to be able to form new bone at the defects/irregularities 2, 3, 4, 5 and 6. In accordance with the invention, new bone formations 11, 12, 13, 14 and 15 will be created so that the implants 8, 9 and 10 acquire the necessary or accepted embedding in newly formed bone and stability. In connection with the formation of new bone, spaces 17, 18, 19, 20 and 21 will be formed so that body fluids containing cells, for example stem cells, penetrate into each space from the jaw bone and possibly from its periosteum 21. In a first embodiment,

said periosteum and the soft tissue of the jaw bone can stretch across the defects/irregularities to form the spaces 17, 18, 19, 20 and 21. Alternatively or in addition to this, strengthening elements, for example 5 membranes 22, can be used. Said strengthening elements can be stiff and can be shaped or folded over the defects. Alternatively, they can be anchored to the side surface of the jaw bone by means of securing members/screws 23, 24. The strengthening element may 10 possibly be provided with GSS 22a on the inner surface 22b. In the illustrative embodiment according to Figure 1, the implants 9 and 10 have a degree of exposure to the spaces 19 and 21, which degree of exposure is shown by the angle  $\alpha$ , which can have values of up to  $180^\circ$  for 15 example. Each implant is provided with one or more concentrations of GSS, which concentration or concentrations has/have been shown by 25 in exaggerated thickness for reasons of clarity. The other implants too are provided with said concentrations or layers of 20 GSS, and the concentration or layer on the implant 10 is indicated by 26. During the stage of incorporation or the new bone formation, body fluids can be secreted in accordance with the above and can penetrate into said spaces where at the same time GSS is released and 25 interacts with the cells in the body fluids, and the formation of bone is thus effected in a manner known per se. In the illustrative embodiment according to Figure 1, the implant 8 has been provided with a strengthening element which extends over the top 30 surface of the implant. The strengthening element is indicated by 27 and in this case has projecting anchoring members 27a which extend radially outward, for example, from the center part of the strengthening element. The strengthening element can have two or more 35 projecting portions and, in the illustrative embodiment shown in Figure 1, it has four portions. At each projecting portion, the strengthening element can be screwed into the jaw bone with anchoring

members/screws, for example screws 28, 29, the screw 28 having been screwed into the jaw bone in the direction toward its horizontal plane, and the screw 29 having been screwed in the direction toward a vertical plane 5 of the jaw bone. The screw 29 is applied on the outer surface of the jaw bone. A tightening screw 30 for one portion is secured on the vertical inner surface of the jaw bone. As the new formation of bone by interaction between cells in secreted body fluid and released GSS 10 can take place in a manner known per se, this will not be described in detail here. The implants can be made of titanium, ceramic, etc., and the strengthening elements can be made of durable material, for example polymer membrane, titanium, stainless steel, etc. The 15 strengthening elements can be secured in a releasable or permanent manner. By means of the formation of new bone in said spaces, a considerably evened-out front surface 1a of the jaw bone is obtained, and this is also the case with the inner vertical surface 1b which 20 is made even by means of the new bone formations 14 and 15. The implants can be threaded and can be of the self-tapping type. Alternatively, thread taps can be used to form the jaw bone holes 1d, 1e, into which the implants 8, 9 and 10 are thereafter screwed.

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In accordance with Figure 2, defects or irregularities 31, 32 and 33 may also be present in the vertical plane, i.e. coinciding with the plane of the paper in Figure 2. There may be a requirement for implants 34, 30 35 to be able to be placed at the recesses 31 and 32. The implants 36, 37 are fitted at elevated parts 38, 39 along the jaw bone. The implants 36 and 37 therefore 35 have a greater degree of recessing in the jaw bone than do the implants 34 and 35. Thus, for example, the implant has first portions 36a which are recessed in the jaw bone, and second portions 36b which are exposed from the jaw bone. The first portions can have a height H' which is, for example, 50-80% of the total height H

of the implant. The height  $H''$  of the exposed portion 36b has a degree of exposure corresponding to said degree of recessing. The implant 34 has a first portion which has a height  $h'$  which is relatively small in relation to the total height  $h$  of the implant. The exposed part 346 has a height  $h''$  which can be of prominent size. The first portion  $h'$  can have values of between 10 and 20% of the total height  $h$ . In accordance with the concept of the invention, the new bone formation 40, 41 will be arranged so that the function of new bone formation affords a leveling in the horizontal plane of the jaw bone, cf. the top surfaces 42 and 43 which adjoin the upper surfaces 44 and 45 of the top surface of the jaw bone structure. In this case too, the soft tissue 47, possibly with periosteum, can be used to create a space for the formation of new bone. A strengthening element 46 can be included or replace the soft tissue and periosteum function at the new bone formation 40, 41. The strengthening element is in this case provided with a top part 46a and with arm-shaped members 46b which extend away from said top part 46a. The implants 34, 35, 36 and 37 can be provided with different amounts of GSS or preferably different concentrations along the circumference and/or height. The principle is in this case such that the parts of the implant exposed in the initial stage bear a greater amount or greater concentration of GSS than those parts which extend within the jaw bone/the jaw bone hole. In the case of low degrees of recessing in the jaw bone for certain implants (cf. implants 34 and 35), said strengthening or fixing element 46 can be used to stabilize the implant during the stage of incorporation. The design of the strengthening element is dependent on the jaw bone structure, on the shape of the implant and on its extent within the jaw bone.

Figure 3 shows an arrangement where a completely resorbed jaw bone 48 is to be provided with implants

49, 50, 51 and 52. On account of the resorption or the absence of jaw bone, it is necessary to obtain a level-raising effect by means of the above-indicated new formation of bone. The implants are initially anchored 5 in the remaining jaw bone via their first portions (cf. above). The upwardly directed second portions can be covered with soft tissue, possibly with periosteum 53 and/or a strengthening element 54 which can serve as a stabilizing element for the implants during 10 incorporation. By means of the arrangement shown, closed spaces 53, 54, 55, 56 and 57 are obtained. In accordance with the above, body fluid can be secreted from the jaw bone, and from the possibly used soft tissue and periosteum, and can penetrate into said 15 spaces. In accordance with the above, the implants 47, 50, 51 and 52 are charged or provided with GSS which, when released from the implants, takes part in the interaction with the body fluids in order to form new bone. In accordance with Figure 3, new bone 58, 59, 60 20 and 61 has formed in the spaces. The new bone formation preferably results in the level being raised along the entire extent of the jaw bone. The implants are fixed via the new bone formation and, after incorporation, acquire stable positions in the jaw bone. In some cases 25 it may be desirable to complete the space between the implant and the bone/soft tissue with bone substitute, for example autologous bone, allogenic bone, xenografts and/or synthetic substances.

30 The invention is not limited to the embodiment shown above by way of example, and instead it can be modified within the scope of the attached patent claims and the inventive concept. The implants are used as supports for dental constructions, for example a bridge which 35 has been symbolized by 62 in Figure 2.

Reference may be made here to patent applications submitted to the Swedish patent office on the same day

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as the present patent application and by the same Applicant and inventor. Said applications have the following titles:

- 5    a) "Arrangement for using osteoinductive or bioactive material to induce bone and/or increase the stability of implants in the jaw bone, and an implant intended for this purpose".
- 10   b) "Arrangement for using bioactive or osteoinductive material to build up a bone-based lateral support for implants in the jaw bone".
- 15   c) "Arrangement for implants bearing growth-stimulating substance or substances, and one such implant".
- 20   d) "Arrangement for increasing the stress resistance of implants, and one such implant".

## PATENT CLAIMS

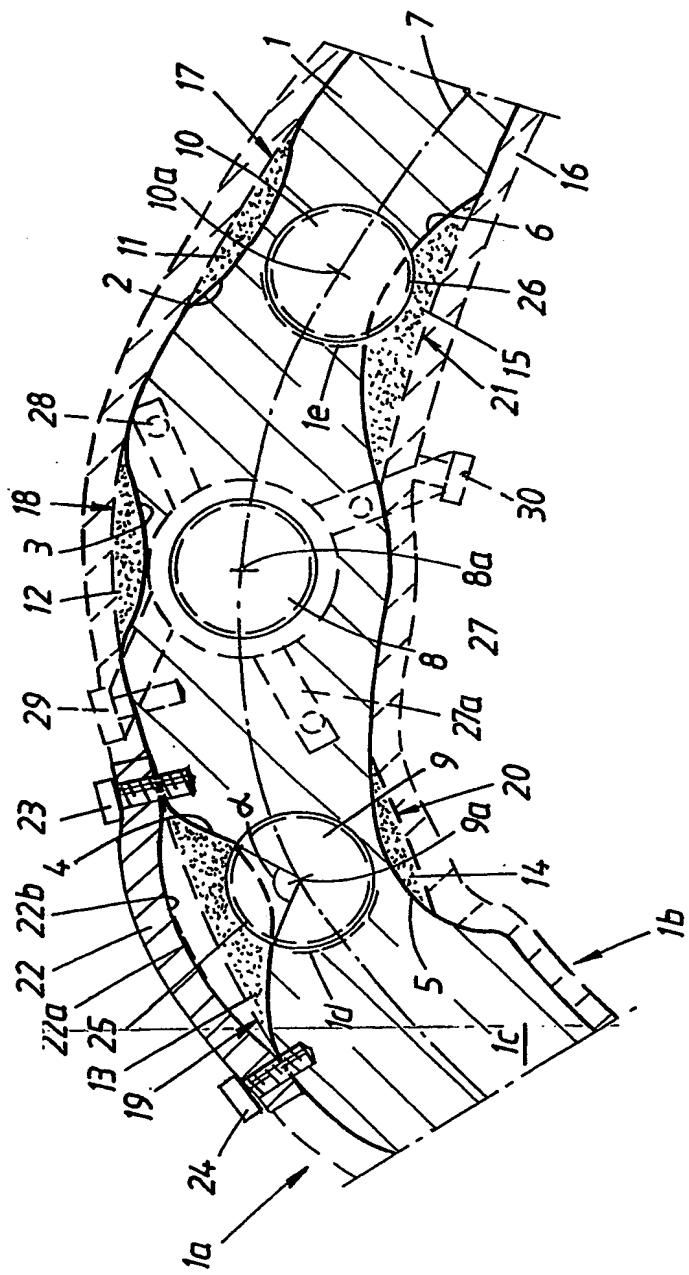
1. An arrangement of two or more implants (8, 9, 10) arranged in succession in the jaw bone (1) and bearing or comprising growth-stimulating substance(s), here called GSS, which, as a function of secretion of body fluid at the implants, is/are intended to be released and form new bone (11, 12, 13, 14, 15) around the implants, characterized in that the implants are designed to work with a release process for GSS, permitting a leveling-out effect along the extent of the jaw bone in the horizontal and/or vertical direction and/or a level-raising effect in the vertical direction.
2. The arrangement as claimed in patent claim 1, characterized in that, in the case where the jaw bone (1) has one or more recesses (31, 32) in the horizontal section and one or more first implants (34, 35) are arranged at one or more recesses, the release function is greater on or at the implant or implants fitted at the recess or recesses compared to the implant or implants arranged at a higher portion or higher portions (38, 39) of the jaw bone.
3. The arrangement as claimed in patent claim 1 or 2, characterized in that the release function is designed to raise the level along the entire jaw bone (1).
4. The arrangement as claimed in patent claim 1, 2 or 3, characterized in that the implants can be covered with the jaw bone's soft tissue and, if appropriate, the periosteum (16) belonging to the latter.

5. The arrangement as claimed in patent claim 4, characterized in that one or more strengthening elements, for example polymer membranes or  
5 titanium plates, are arranged in connection with the jaw bone and the soft tissue/periosteum (16).
10. The arrangement as claimed in patent claim 5, characterized in that the strengthening element (27, 46) or strengthening elements is/are of a temporary or permanent nature, and, in the case of a permanent nature, the element or elements is/are complementary elements which can be applied to a dental structure, for example a bridge (62)  
15 connectable to the implants.
20. The arrangement as claimed in patent claim 5 or 6, characterized in that each strengthening element (27, 46) can be secured to the jaw bone by means of securing members, for example one or more screws (28, 29).
25. The arrangement as claimed in patent claim 5, 6 or 7, characterized in that the strengthening element (46) extends over the top face of the jaw bone or along the vertical side or sides of the jaw bone.
30. The arrangement as claimed in patent claim 8, characterized in that each strengthening element is provided with arm-shaped members (27) via which the strengthening element can be anchored to the jaw bone.
35. 10. The arrangement as claimed in any of patent claims 1-9, characterized in that, in an initial stage, first implants (34) have first outer portions (34a) or outer surfaces which have a greater

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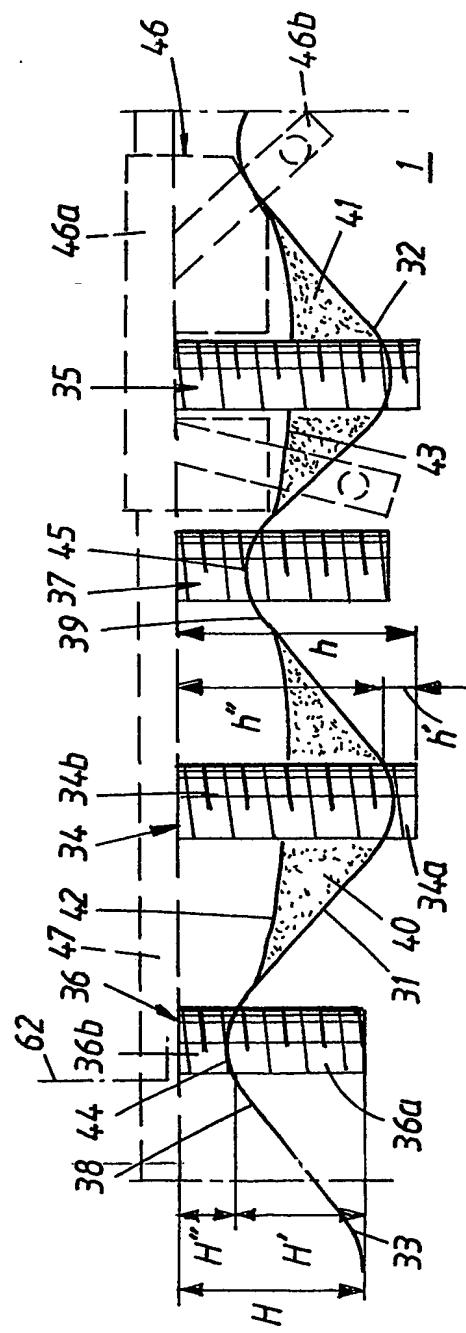
degree of exposure than outer portions or outer surfaces (36b) on second implants (36).

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*FIG. 1*

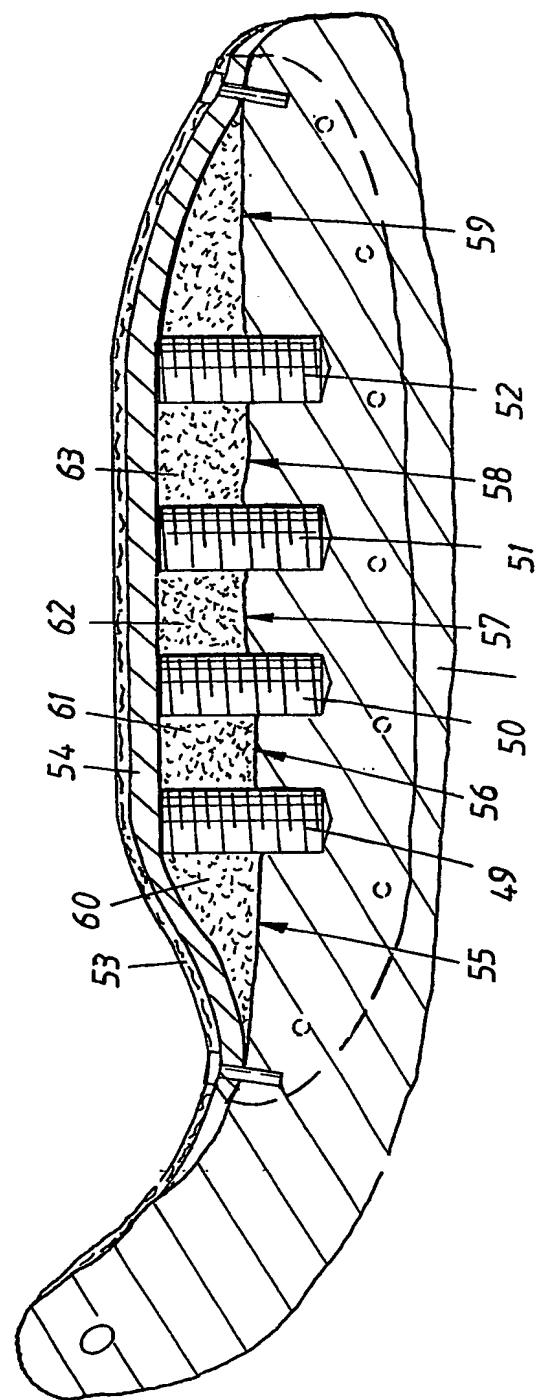
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FIG. 2



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FIG. 3



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 03/01109

## A. CLASSIFICATION OF SUBJECT MATTER

**IPC7: A61C 8/00, A61L 27/54**

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

**IPC7: A61C, A61L**

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

**SE, DK, FI, NO classes as above**

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 0072775 A1 (NOBEL BIOCARE AB (PUBL)), 7 December 2000 (07.12.00)  --	1-10
A	WO 0072776 A1 (NOBEL BIOCARE AB (PUBL)), 7 December 2000 (07.12.00)  --	1-10
A	WO 0072777 A1 (NOBEL BIOCARE AB (PUBL)), 7 December 2000 (07.12.00)  -----	1-10

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	
"A"	document defining the general state of the art which is not considered to be of particular relevance
"E"	earlier application or patent but published on or after the international filing date
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O"	document referring to an oral disclosure, use, exhibition or other means
"P"	document published prior to the international filing date but later than the priority date claimed
"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X"	document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y"	document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&"	document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 October 2003	09-10-2003
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. + 46 8 666 02 86	Authorized officer  Jack Hedlund/E1s Telephone No. + 46 8 782 25 00

## INTERNATIONAL SEARCH REPORT

Information on patent family members

06/09/03

International application No.

PCT/SE 03/01109

Patent document cited in search report	Publication date		Patent family member(s)	Publication date
WO 0072775 A1	07/12/00		AU 1589900 A AU 5260700 A CA 2372035 A CA 2373932 A EP 1191900 A EP 1241937 A JP 2003500158 T SE 515695 C SE 9901973 A	22/05/00 18/12/00 11/05/00 07/12/00 03/04/02 25/09/02 07/01/03 24/09/01 01/12/00
WO 0072776 A1	07/12/00		AU 1433300 A AU 5260800 A CA 2373701 A EP 1191901 A JP 2003500159 T SE 514202 C SE 9901974 A	29/05/00 18/12/00 07/12/00 03/04/02 07/01/03 22/01/01 01/12/00
WO 0072777 A1	07/12/00		AU 5260900 A CA 2373934 A EP 1055096 A EP 1196110 A IL 137908 D JP 2003500160 T SE 514323 C SE 9901971 A US 6415715 B	18/12/00 07/12/00 29/11/00 17/04/02 00/00/00 07/01/03 12/02/01 01/12/00 09/07/02